have approved marketing of the device and thus plaintiffs would not have been injured. The Court explained that "although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim" (531 U.S. at 353), and held the plaintiffs' claims to be impliedly preempted by the MDA. Fraud on a federal agency, the Court held, was not a matter historically of state concern, and "fraud-on-the-FDA claims would * * * cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court." *Id.* at 351.

B. The extensive regulatory history of the Activa device prior to its PMA approval.

Both *Lohr* and *Buckman* stressed the "thorough review" (*Buckman*, 531 U.S. at 344; see also *Lohr*, 518 U.S. at 477) that Class III medical devices must undergo before obtaining approval from the FDA pursuant to the PMA process. The path to approval of the Activa Tremor Control System (Activa) at issue in this case demonstrates the thoroughness of that review.

The Activa is a surgically implanted neurological device designed to control tremors, especially those resulting from Parkinson's Disease. The Activa is classified as a Class III medical device under the MDA. Pet. App. 2a. Medtronic submitted a PMA application for the Activa on April 30, 1996.[2] The PMA application, as amended and supplemented over the following 15 months, contained large quantifies of scientific information, including data from preclinical, ani-

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[2] This description of the PMA process resulting in FDA approval of the Activa is based on the affidavit of Lisa L. Pritchard, which is contained in Medtronic's Supplemental Appendix in the Seventh Circuit (SA), at 136–150. See also Pet. App. 2a–3a.

mal, and human studies, as well as material evaluation and biostability studies. The PMA application also provided extensive information on the device's hardware and software design, in addition to the production and quality-control processes that would be used in the device's manufacture. Similarly, the PMA application contained full copies of proposed labeling materials, including product labels, physician manuals, and patient manuals.

The Activa PMA application underwent exhaustive review by the FDA staff. The FDA made various inquiries of Medtronic, and the initial application was modified and supplemented on several occasions in response.[3] In addition, the application was referred to an FDA Advisory Panel, a group of outside experts—including physicians and biomedical engineers—convened by the agency to review the application and recommend whether it should be granted or denied.

Having "run[] the gauntlet of the PMA process," *Lohr*, 518 U.S. at 494, the Activa PMA application was granted on July 31, 1997. The FDA approval was subject to various conditions, including the requirement that Medtronic, before actually marketing the device, submit "copies of all approved labeling in final printed form." SA 159. As part of that labeling, "[t]he FDA * * * required Medtronic to list specific warnings regarding 'electrocautery' and 'diathermy' in its manuals for physicians and patients." Pet. App. 3a.[4] The

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[3] For example, the "proposed labeling materials were amended to meet the FDA's specific concerns and requirements before [the PMA application] was approved." SA 142.

[4] The FDA-mandated warning for physicians stated:

> Electrocautery–Electrocautery can cause temporary suppression of pulse generator output and/or reprogramming of the pulse generator. If use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the pulse generator and lead as possible.

FDA also required Medtronic, pursuant to 21 C.F.R. § 821.1, to track the name and contact information of patients implanted with the Activa, and, pursuant to 21 C.F.R. § 814.82(a)(9), to submit written reports to the FDA if it became aware of information reasonably suggesting that the Activa "may have caused or contributed to a death or serious injury." Pet. App. 3a; SA 159, 164.

C. Petitioners' case in the lower courts.

Petitioner Jack McMullen (McMullen) was implanted with an Activa Tremor Control System in May 2000.[5] Pet.

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* * *

> Diathermy–The effects of diathermy on patients with an implanted neurostimulation system are unknown. Use of diathermy directly over an implanted lead or pulse generator is not recommended since internal components may be damaged.

SA 171–172. The FDA-mandated warning for patients stated:

> Tell your dentist where your IPG is implanted, so he or she can take precautions with dental drills and ultrasonic probes used to clean your teeth. These devices should not be used directly over the implant site.
>
> Therapeutic ultrasound, electrolysis, radiation therapy, and electrocautery also should not be used directly over the implant site.
>
> . . .
>
> Diathermy treatments that are sometimes used for muscle relaxation may affect the neurostimulator output and/or damage its electronics.

Pet. App. 3a–4a.

[5] McMullen initially alleged that he had received a different device, the Activa Parkinson's Control Therapy, which at the time of McMullen's implantation had been approved by the FDA through

App. 4a. As petitioners acknowledged in the district court and again in the court of appeals, the Activa was, at least initially, "extremely effective in eliminating Jack McMullen's symptoms of Parkinson's disease." SA 739. See also Appellants' Ct. App. Br., at 7 (same).

In March 2001, McMullen underwent a dental procedure which possibly involved diathermy or electrocautery.[6] Pet. App. 4a. Subsequent thereto, McMullen allegedly "experienced a tremendous exacerbation of his Parkinson's symptoms." Pet. 7.

Approximately two months before McMullen's dental procedure, Medtronic received an anecdotal report that another Activa recipient had been injured while receiving diathermy treatment in the course of a dental procedure. Pet. App. 4a, 22a. On May 18, 2001, approximately two months after McMullen's dental procedure, Medtronic, having investigated that anecdotal report, sent a letter to Activa recipients and their physicians warning that exposure to diathermy

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the "investigational device exemption" (IDE) process instead of the PMA process. The district court concluded that "the medical records of Mr. McMullen and other uncontroverted evidence establish the device implanted in Mr. McMullen on May 17, 2000, was the Activa Tremor Control * * * System." Pet. App. 23a. McMullen did not challenge that determination in the court of appeals. As the Seventh Circuit noted, "[a]ccordingly, any arguments based on [the prior] factual assertion have been forfeited." Pet. App. 4a n.2.

[6] In the district court, there was a dispute as to which of these two procedures was involved. However, because the FDA had required Medtronic to issue specific warnings with respect to both procedures, see note 4, *supra*, "[t]he distinction between the two procedures"—both of which use electricity—"is not important for the purposes of this case." Pet. App. 3a n.1.

could result in serious injury or death. Pet. App. 5a, 22a.[7] Federal regulations permitted, but did not require, Medtronic to send that warning without prior FDA approval. See 21 C.F.R. § 814.39(d) (providing that "[l]abeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device" "*may* be placed into effect by the applicant prior to the receipt * * * of a written FDA order approving the PMA supplement") (emphasis added); see also Pet. App. 13a.[8]

1. The District Court proceedings.

On December 5, 2002, petitioners filed suit in Indiana state court alleging that Medtronic violated a state-law "post-sale duty to timely warn" of newly discovered dangers by not issuing the revised diathermy warning until May 2001. Pet.

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[7] The warning sent to patients advised them to "[i]nform anyone treating you that you CANNOT have any shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy * * * anywhere on your body because you have an implanted neurostimulation system" and that "[e]nergy from diathermy can be transferred through your implanted system" and thus "cause tissue damage" which could "result in severe injury or death." Pet. App. 5a. That warning further advised that "[d]iathermy can * * * damage parts of your neurostimulation system," with a resultant "loss of therapy from your neurostimulation system." *Ibid.*

[8] As a general rule, the manufacturer of an approved Class III device must "submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device." 21 C.F.R. § 814.39(a). Medtronic's warning letter was permitted under one of the limited exceptions to this rule, contained in § 814.39(d)(2)(i), pursuant to which a manufacturer may strengthen certain types of warnings on a previously approved device upon *submission* of a PMA Supplement explaining the change. Thus, Medtronic also submitted a PMA Supplement under 21 C.F.R. § 814.39(a) seeking FDA approval of permanent labeling changes incorporating the new warning. On June 22, 2001, the FDA approved the new warning. Pet. App. 5a–6a.

9.[9] Medtronic promptly removed the action to the United States District Court for the Southern District of Indiana. Pet. App. 17a.

The parties filed cross-motions for summary judgment. Pet. App. 16a. Medtronic argued that it was entitled to summary judgment because petitioners' state-law action was preempted under 21 U.S.C. § 360k(a), which, with respect to medical devices, provides that "no State * * * may establish * * * any requirement * * * which is different from, or in addition to, any requirement applicable under this chapter."

In resisting Medtronic's motion for summary judgment, petitioners did not dispute that the PMA process imposed specific federal requirements applicable to the Activa; nor did they dispute that the purported state-law duty to warn that they sought to enforce would in application constitute a specific state requirement with respect to the Activa. Indeed, far from denying the existence of either federal or state requirements, petitioners told the district court that "[t]he essence of this case is Medtronic's egregious failure to follow *corresponding state and federal requirements* to timely warn recipients of its deep brain stimulation systems of the dangers of severe injury or death when Medtronic became aware of such dangers." SA 75 (emphasis added). According to petitioners, their post-sale duty-to-warn claim was not preempted because "these state requirements are fully consistent with the federal tracking and notification requirements under FDA regulations." SA 68.

The district court rejected this argument, finding that "there is a logical disconnect between the federal regulation to track recipients of a device, and a duty, not set forth in any federal regulation pertaining to this device, to contact all recipients of that device upon the discovery of an adverse reac-

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[9] Petitioners also asserted a derivative claim for loss of consortium. Pet. App. 14a.

tion * * * that, as it appears to be in this case, was the subject of product warnings approved by the FDA's PMA process." Pet. App. 36a. Noting that Congress intended § 360k(a) "to be a 'general prohibition on non-Federal regulation,'" Pet. App. 28a (quoting H.R. REP. No. 94-853, at 45), the district court granted Medtronic summary judgment on preemption grounds (and simultaneously denied petitioners' cross-motion), holding that "[t]he failure to warn claim asserted by the McMullens presupposes a duty 'in addition to' the specific federal requirements imposed on Medtronic through the Activa's PMA process and approval." Pet. App. 36a.

2. The Court of Appeals' decision.

On appeal to the Seventh Circuit, petitioners again conceded the existence of specific state and federal requirements, asserting that Medtronic had a post-sale duty to warn "pursuant to both federal requirements and the requirements of state law." Appellants' Ct. App. Br. 8–9. Rather than deny the existence of either state or federal requirements for purposes of preemption under § 360k(a), petitioners instead argued that their post-sale duty-to-warn claim was not preempted because it was a state common-law action purportedly "seeking to enforce *parallel* federal requirements." *Id.* at 10 (emphasis added).

In affirming summary judgment for Medtronic on preemption grounds, the Seventh Circuit recognized that § 360k(a)

> sets three conditions for preemption: (1) there must be a "requirement" that a state "establish[es] or continue[s] in effect, with respect to a device intended for human use"; (2) there must be a relevant federal requirement under the FDCA applicable to the device at issue; and (3) the state "requirement" must be "different from, or in addition to," the federal requirement.

Pet. App. 8a. The court noted that "the parties agree that the first condition is satisfied" and that "[t]here also is no dispute as to the second condition." *Id.* at 8a–9a. Thus, satisfaction of the third condition—the existence of a state requirement "different from, or in addition to" the federal requirement—was "the only one contested in this case." *Id.* at 10a.

The Seventh Circuit acknowledged that *if* "Medtronic was obligated, under parallel state and federal laws, to send a 'timely' additional warning" respecting the dangers of diathermy to Activa recipients, "then the state requirements will not be different from, or in addition to, the federal requirements and McMullen's claim will not be preempted pursuant to 360k(a)." *Id.* at 11a. However, the Seventh Circuit found that this was not the case.

As the court of appeals explained, "McMullen point[ed] to two federal regulations as the basis for his contention that federal law creates a duty that is equivalent to the state-law duty underlying his claim." Pet. App. 12a. Specifically, McMullen pointed to "21 C.F.R. § 821.1, which requires manufacturers to track recipients of devices; and § 814.39, which permits manufacturers to enhance warnings pending approval of a proposed change to an earlier-approved warning." *Ibid.* But, the court held, "[c]ontrary to McMullen's contention, * * * neither of these regulations, considered alone or together, imposed upon Medtronic a duty to issue an additional warning between January and March 2001." *Ibid.* In particular, the tracking requirement imposed by 21 C.F.R. § 821.1 "enables warnings to be issued and devices to be recalled if the Secretary [of Health and Human Services] decides that it is appropriate to do so," but "does not impose on the manufacturer the obligation to make warning or recall decisions unilaterally." *Id.* at 13a. Similarly, 21 C.F.R. § 814.39 "*permits*, but does not *require*, a manufacturer to provide interim supplemental warnings pending approval by the FDA." *Id.* at 13a–14a (emphasis added).

Consequently, the court of appeals concluded, "[b]ecause McMullen's claim based on the common-law post-sale duty to warn would impose on Medtronic a requirement that is in addition to federal requirements," that claim "is preempted pursuant to 21 U.S.C. § 360k(a)." *Id.* at 14a.

REASONS FOR DENYING THE WRIT

There is no reason for this Court to grant certiorari in this case. As petitioners acknowledge, there is no division whatsoever among the lower courts on the question presented here. Although petitioners allude to *other* issues on which there is some, albeit minor, conflict among the lower courts, petitioners have waived any argument based on those issues—which in any event would not warrant this Court's attention. Finally, the decision below is plainly correct. Thus, further review is not warranted.

I. There Is No Conflict Among The Lower Courts On Any Question Presented In This Litigation.

Petitioners assert that "review is warranted to resolve the conflict among the circuit courts and various state courts regarding the preemptive effect of the [Medical Device Amendments] on state common law causes of action." Pet. 10. But in fact, this case does not implicate any such conflict.

A. Petitioners acknowledge that there is no division among the lower courts regarding the preemption of post-sale duty-to-warn claims.

As discussed above (at page 3), in *Lohr* this Court explained that there are three relevant issues for purposes of a preemption analysis under § 360k(a)—the existence of specific federal requirements on a medical device, the existence of specific state-law requirements on the device, and some difference between those two sets of requirements. See also Pet. App. 8a.

Throughout this litigation, petitioners have litigated only the third of these issues. They have never disputed that the

PMA process creates specific federal requirements as to the Activa device or that liability in a state-law tort suit would also impose requirements on the device. Rather, the only issue here is whether the federal and state-law requirements impose *identical* obligations on Medtronic to provide its customers with post-sale warnings. See pages 10–11, *supra*; Pet. 9, 15, 20.

As to this question, petitioners readily admit that there is no circuit split or other divide among the lower courts. Rather, they acknowledge that, with the exception of the Seventh Circuit in this case, the issue is one that "has not really been directly addressed by the circuit courts." See Pet. 20.[10] Nor has the question been addressed by state courts. Absent some indication that this issue has caused confusion among the lower courts, there is no reason for this Court's

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[10] In fact, post-sale duty-to-warn claims have been addressed, at least indirectly, by several circuits. In each instance, the court of appeals found the claim to be preempted. In *Cupek*, the plaintiffs sought leave to amend the complaint to include a post-sale duty-to-warn claim. The district court denied the request, holding the claim preempted and the proposed amendment therefore futile. The Sixth Circuit affirmed. See 405 F.3d at 423–424. In *Horn*, the FDA, in its *amicus* brief, characterized the plaintiff's complaint as including a post-sale failure-to-warn claim. 376 F.3d at 166 n.5. The Third Circuit, at the FDA's urging, held the plaintiff's claims to be preempted. *Id.* at 177. In *Kemp*, the plaintiffs argued on appeal that their failure-to-warn claim should have been construed as asserting "a wholly separate and distinct claim that defendant acquired information subsequent to the FDA approval * * * and before implantation of the device that would lead a reasonable manufacturer to warn patients and the medical community." 231 F.3d at 236–237. However, the Sixth Circuit found the argument to be untimely and therefore did "not address the preemptive effect, if any, of § 360k on a claim for breach of a manufacturer's duty under state law to warn patients or the medical community of potential risks of a particular medical device based on information obtained subsequent to FDA approval of the device." *Id.* at 237.

review—especially given the obvious correctness of the decision below (see Part III, *infra*).

B. Petitioners have waived any argument based on the vestigial circuit splits that do exist as to the proper scope of preemption in the PMA context under *Lohr*.

Notwithstanding the conceded absence of a circuit split on the only question presented here, petitioners argue that certiorari should be granted in order to address what petitioners characterize as "the widely varying interpretation of the Court's decision in *Lohr*." Pet. 10. Petitioners' suggestion is misguided. Whatever vestigial disagreements there may still be in the lower courts over the proper application of *Lohr* in the PMA context, those disagreements are not presented by this case.

Although petitioners greatly exaggerate the extent and significance of these conflicts, as we discuss in Part II below, there is some, albeit minor, conflict among the lower courts as to two of the three factors that, under *Lohr*, are to be considered when determining whether preemption exists pursuant to § 360k(a)—specifically, whether the PMA process imposes specific federal requirements on a medical device, and whether liability in a state-law tort suit would impose a specific state-law requirement on a medical device.

However, at every stage of the proceedings in this litigation—in the district court, in the court of appeals, and now in this Court—petitioners have *conceded* that the PMA process imposed specific federal requirements applicable to the Activa and that their common-law action would, if successful, impose specific state requirements on the device. See Pet. 20 (referring to the "requirements promulgated by the FDA" through the PMA process); *id.* at 9 (referring to "state law requirement to timely warn"); see also pages 10–11, *supra* (discussing petitioners' concessions in the courts below); Pet. App. 8a-9a (noting that "the parties agree" that state-law tort

suits impose requirements on medical devices and that "[t]here also is no dispute" between the parties that the PMA process imposes specific federal requirements on the device).

Having conceded the existence of specific federal requirements imposed through the PMA process, and having conceded that their tort action would, if successful, impose specific state-law requirements, petitioners have waived any argument that the PMA process does not impose preemptive requirements as well as any argument that common-law claims, by their nature, cannot impose state requirements subject to preemption under 21 U.S.C. § 360k(a).[11] As a result, even if the Court wished to do so, this case does not provide an opportunity to resolve the vestigial disagreements over the proper interpretation of *Lohr*.

II. Even Absent Petitioners' Waiver, Review Of The Vestigial Circuit Splits That Exist As To The Application Of *Lohr* In The PMA Context Would Not Be Warranted.

Review would not be warranted even if this case presented the Court with an opportunity to resolve the minor circuit splits that exist as to the application of § 360k(a) in the PMA context. In fact, on at least four occasions in the last five years this Court has denied petitions for certiorari that provided the Court an opportunity to address these issues. See *Knisley* v. *Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Brooks* v. *Howmedica, Inc.*, 535 U.S. 1056 (2002); *Martin* v. *Medtronic, Inc.*, 534 U.S. 1078 (2002); *Kemp* v. *Medtronic, Inc.*, 534 U.S. 818 (2001).

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[11] This Court will not consider questions presented in the petition for a writ of certiorari that were not presented below. See, *e.g.*, *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 56 n.4 (2002); *Delta Airlines* v. *August*, 450 U.S. 346, 362 (1981); *United States* v. *Ortiz*, 422 U.S. 891, 898 (1975).

A. Any disagreements among the lower courts are minimal and diminishing.

This Court held in *Lohr* that § 360k(a) has preemptive effect only where there is a "specific" state requirement that is "different from, or in addition to" a "specific" federal requirement. 518 U.S. at 500. See also *id.* at 506–507 (Breyer, J., concurring). We acknowledge that there is some disagreement in the lower courts over whether the PMA process establishes "specific" federal requirements. There is also some disagreement in the lower courts over whether a state common-law action would, if successful, impose "specific" state requirements.

These disagreements, however, are the increasingly stale product of a few aberrational decisions issued shortly after *Lohr*. Moreover—given the guidance provided by this Court's subsequent decisions in *Bates* v. *Dow Agrosciences LLC*, 125 S. Ct. 1788, 1798 (2005), *Buckman*, and *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000), and the additional guidance provided by the FDA in an *amicus* brief it filed in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004)—whatever minimal disagreements still remain are diminishing and likely to disappear altogether without further intervention by this Court.

1. The great weight of authority, and *all* recent authority, holds that the PMA process imposes specific federal requirements that have preemptive force. See Pet. App. 9a–10a; *Cupek*, 405 F.3d at 424; *Horn*, 376 F.3d at 171–73; *Brooks*, 273 F.3d at 799; *Martin*, 254 F.3d at 585; *Kemp*, 231 F.3d at 226-27; *Mitchell*, 126 F.3d at 911; see also *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green* v. *Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

In contrast to the decisions of the Third, Fifth, Sixth, Seventh, and Eighth Circuits, as well as those of the Pennsylvania, Rhode Island, and Texas supreme courts, there is

only one federal court of appeals decision and only one state supreme court decision, cf. S. Ct. R. 10, to hold that the requirements imposed through the PMA process are not preemptive—*Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and *Weiland* v. *Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999). Those decisions, however, are relatively old, internally confused, and unlikely to survive even absent this Court's intervention.

For example, the *Goodlin* court found that the PMA process "is clearly specific to the device under review" and that the FDA's Conditions of Approval "constitute specific federal requirements," 167 F.3d at 1376, yet then somehow concluded that the requirements were not "applicable under [the MDA] to the device,'" *ibid.* (quoting 21 U.S.C. § 360k(a)(1)), and did not establish "a specific requirement that applies to a particular device," *id.* at 1377. The decision is not only internally inconsistent and factually incorrect, but also contrary to *Lohr*. The *Goodlin* court denied preemptive effect to the concededly specific federal requirements, apparently because the FDA's Conditions of Approval were "not promulgated * * * with respect to [a] 'particular device.'" *Ibid.* Yet, so long as the specific federal requirement is applicable to a given device, *Lohr* does not demand that the requirement be applicable *exclusively* to that device. In fact, the FDA has frequently held that federal requirements have preemptive effect even though they apply to a wide array of devices. See, *e.g.*, Final Rule, *Medical Devices*, 45 Fed. Reg. 67,321, 67,322 (Oct. 10, 1980).

Weiland, in contrast, found that no aspect of the PMA process is specific. See 721 N.E.2d at 1152. It based that conclusion on two false premises, however: First, the court held that "[p]remarket approval imposes no ascertainable substantive requirement on the manufacture or design of the device" (*ibid.*)—a statement that is untrue both in general (see 21 C.F.R. § 814.80 (prohibiting the manufacturer from making any change without FDA authorization to a device

that has been approved by the agency through the PMA process if such change would affect the device's safety or effectiveness)), and in this case, where the FDA required specific modifications of the Activa's labeling prior to PMA approval (see note 3, *supra*). Second, the court held that the PMA process allows the FDA to assure only "the *minimal* safety of medical devices" (*id.* at 1153) (emphasis added), a holding inconsistent with *Lohr*, which understood the "reasonable assurance" of safety and effectiveness to be a significant hurdle. In light of *Buckman*'s repetition of the significance of PMA review, see 531 U.S. at 343, the *Weiland* decision is plainly incorrect.

In the seven years since they were decided, no other court of appeals and no other state supreme court has joined either the Eleventh Circuit's decision in *Goodlin* or the Illinois Supreme Court's decision in *Weiland*. Given their internal flaws, this Court's reminder that the PMA process subjects a device to "thorough review," *Buckman*, 531 U.S. at 344, and the FDA's recent declaration that "through the PMA approval process [the FDA] certainly establishes 'specific requirements' applicable to a 'particular device,'" Brief for United States as *Amicus Curiae* (U.S. Br.), 2004 WL 1143720, at *16, filed in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (2004) (see also pages 22–24, *infra*), there is no reason to believe that any court will repeat the errors in *Goodlin* or *Weiland*.

2. On the state side of the *Lohr* preemption equation, the great weight of authority, and *all* recent authority, holds that state common-law claims can impose specific requirements and are thus subject to preemption under § 360k(a). See, *e.g.*, Pet. App. 9a; *Cupek*, 405 F.3d at 424; *Horn*, 376 F.3d at 173–177; *Brooks*, 273 F.3d at 799; *Martin*, 254 F.3d at 584; *Kemp*, 231 F.3d at 224; *Mitchell*, 126 F.3d at 913–914; *Papike* v. *Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376–377; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117–118.

This view is plainly correct under *Lohr* and this Court's subsequent decisions in *Geier* and *Bates*. In *Lohr*, a majority of this Court held that the Medical Device Amendments, of which § 360k(a) is a part, "will sometimes pre-empt a state-law tort suit," 518 U.S. at 503 (Breyer, J., concurring), because "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Id.* at 504–505; accord *id.* at 509 ("state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA") (O'Connor, J., concurring in part and dissenting in part). Significantly, Justice Stevens, who wrote the plurality opinion in *Lohr*, has himself stated that *Lohr* "recognized that the statutory reference to 'any requirement' imposed by a State * * * may include common-law duties." *Geier*, 529 U.S. at 897 (Stevens, J., dissenting). See also *Geier*, 529 U.S. at 867 (noting that "a majority of this Court" in *Lohr* recognized that state tort actions may be preempted as imposing conflicting "requirements"); cf. *Bates*, 125 S. Ct. at 1798 (noting "the term 'requirements in [7 U.S.C.] § 136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties").

Only one federal court of appeals or state court of last resort, cf. S. Ct. R. 10, has relied on a contrary finding to limit the preemptive scope of § 360k(a)—the Tenth Circuit in *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (1997). *Oja* is one of the earliest appellate decisions to interpret *Lohr*, did not involve a device that had been approved through the PMA process, and plainly misinterprets *Lohr* in a variety of ways.[12]

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[12] The device at issue in *Oja* was approved via the so-called 510(k) process. As this Court noted in *Lohr*, "[t]he § 510(k) notification process is by no means comparable to the PMA process."

For example, the Tenth Circuit never directly considered whether a finding of liability under a state common-law duty would "have 'the effect of establishing a substantive requirement of a specific device'"—even though the court acknowledged that such an inquiry was necessary. 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500 (in turn quoting 21 C.F.R. § 808.1(d)(1))). More importantly, the court failed to appreciate that a majority of this Court had expressly held in *Lohr* that state common-law damages actions impose "requirements" that can be preempted by federal requirements. See *Lohr*, 518 U.S. at 503 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part); *Geier*, 529 U.S. at 867.

This single aberrant decision by a federal court of appeals, rendered shortly after *Lohr*, does not warrant this Court's attention. In the nine years since *Oja*, there has been no movement by any other court toward that court's erroneous analysis. Moreover, given this Court's recent holding in *Bates* that the term "requirements" in the identically-worded FIFRA includes common-law claims, see 125 S. Ct. at 1798, the unanimous view of the other courts of appeals that such claims may be preempted, and the FDA's similar view as expressed in its *amicus* brief in *Horn*, see U.S. Br., 2004 WL 1143720, at *18 ("state tort law judgments do impose a requirement for purposes of preemption under the MDA") (see also pages 22–24, *infra*), there is no reason to believe that the Tenth Circuit would continue to follow *Oja* after further analysis of this Court's holding in *Lohr*.

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518 U.S. at 478–479. On average, the FDA devotes only 20 hours to a 510(k) review, but 1,200 hours to the far more exacting PMA review. See *id.* at 477, 479.

B. The lower courts should be allowed to consider the implications of the FDA's *amicus* brief in *Horn*.

In *Lohr*, this Court recognized that "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect." 518 U.S. at 495–496. The Court further recognized that, as the federal agency to which Congress has delegated the authority to implement the MDA, the FDA "is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' and, therefore, whether it should be pre-empted." *Id.* at 496 (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). Given "the ambiguity in the statute" and "the congressional grant of authority to the agency on the matter contained within it," the Court found it appropriate to "giv[e] substantial weight to the agency's view of the statute." *Ibid.*

The FDA has recently provided authoritative guidance on the scope of § 360k's preemptive effect in the PMA context. At the request of the Third Circuit, the United States submitted an *amicus* brief on behalf of the FDA in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (2004). The FDA's *amicus* brief explains at length and in detail why "FDA pre-market approval for a new medical device preempts state law tort judgments." U.S. Br., 2004 WL 1143720, at *2.

With respect to the federal side of the equation, the FDA stated unequivocally that "through the PMA approval process [the FDA] certainly establishes 'specific requirements' applicable to a 'particular device.'" *Id.* at *16. The FDA noted that "[a]lthough the PMA approval order does not itself expressly reiterate all of the specific features the device's design, labeling, and manufacturing processes must have, it specifically approves as a matter of federal law those features as set forth in the application and binds the manufacturer to produce and

market the product in compliance with the specifications as approved by [the] FDA." *Id.* at *24.

With respect to the state side of the preemption equation, the FDA endorsed the view—subscribed to by a majority of the Justices in *Lohr*—that "state tort law judgments do impose a requirement for purposes of preemption under the MDA when a common law action 'would impose a requirement different from, or in addition to, that applicable under the FDCA.'" *Id.* at *18 (quoting *Lohr*, 518 U.S. at 511 (O'Connor, J., concurring in part and dissenting in part)). The FDA observed that, absent an allegation that the device in question deviated from the requirements imposed by the FDA through the PMA process, "any finding of liability * * * would necessarily rest upon an implicit requirement that [the] device be designed, manufactured, or marketed in a way that differs from the way approved by [the] FDA." *Ibid.*

The FDA also emphasized in its brief the "very strong public policy considerations" that support finding PMA approval preemptive of state common-law claims. *Id.* at *25. According to the FDA—the agency charged with implementing the MDA—"[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices." *Ibid.* As the agency explained, during the PMA process it conducts "a thorough review of a substantial scientific record," *id.* at *16, and performs a "careful balancing" of the benefits and risks associated with a particular device. *Id.* at *29. State tort actions, however, usurp "the central role of [the] FDA" by requiring "lay judges and juries to second-guess the balancing of benefits and risks of a specific device." *Id.* at *25. Because such second-guessing "may disrupt the careful balancing performed by the FDA in the PMA process," *id.* at *29, state common-law claims such as those

asserted in *Horn*—and here—"are preempted under federal law." *Id.* at *31.[13]

Given the agency's "unique role in determining the scope of § 360k's pre-emptive effect," *Lohr*, 518 U.S. at 495–496, the FDA's clear guidance in *Horn* further demonstrates that there is no need for this Court to grant review in this case. The FDA's "reasoned analysis," U.S. Br., 2004 WL 1143720, at *30, is entitled to substantial weight as "the agency's fair and considered judgment on the matter in question." *Auer* v. *Robbins*, 519 U.S. 452, 462 (1997) (deferring to agency interpretation of ambiguous regulation contained in *amicus* brief submitted in dispute between private parties).

There is therefore no reason to believe that the few courts that misinterpreted *Lohr* soon after it was decided will persist in their error. With the benefit of the FDA's *amicus* brief in *Horn*—and this Court's guidance in *Bates*, *Buckman*, and *Geier*—those courts are now likely to join the clear consensus finding state common-law claims that would impose requirements "different from" or "in addition to" the federal requirements imposed through the PMA process to be preempted by federal law. In the unlikely event that those courts, upon reconsideration, choose to adhere to their prior decisions, the Court can grant review at that time.

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[13] To the extent that it requires a manufacturer to issue warnings directly to patients, a state-law post-sale duty to warn, such as that asserted here, would directly conflict with 21 U.S.C. § 360h(a), which expressly authorizes the Secretary of Health and Human Services to withhold a safety notification from patients. See note 14, *infra*. As the FDA explained in *Horn*, patient warnings issued in response to state-law requirements, as opposed to those evaluated and approved by the FDA after careful cost-benefit analysis by healthcare experts, "can harm the public health" by "discourag[ing] appropriate product use," with a resultant "underutilization of beneficial treatments." U.S. Br., 2004 WL 1143720, at *26, *29.

III. The Decision Below Is Plainly Correct.

Review is also unwarranted in this case because the Seventh Circuit was plainly correct in holding that petitioners' state-law failure-to-warn claim is preempted under § 360k(a). By its terms, § 360k(a) preempts, with respect to a medical device, any state-law requirement that is "different from, or in addition to, any requirement applicable * * * to the device" under federal law. Here, there is no dispute that the Activa is subject to federal labeling requirements imposed through the PMA process, and no dispute that petitioners' common-law claim would, if successful, effectively impose a state-law requirement on the device. See pages 10–11, *supra*. Thus, the only issue is whether petitioners' post-sale failure-to-warn claim would, if successful, subject the Activa to a state-law requirement "different from, or in addition to" the federal labeling requirements imposed through the PMA process. There can be no doubt that it would.

In an effort to avail themselves of the "parallel requirements" rule adopted by this Court in *Bates*, and thus to evade the preemptive effect of § 360k(a), petitioners characterize their state common-law action as "an action seeking to enforce parallel federal requirements." Pet. 15. However, this characterization is patently false. Contrary to petitioners' suggestion, neither 21 C.F.R. § 821.1 nor 21 C.F.R. § 814.39 "indicate[s] that Medtronic had a continuing duty to warn" under federal law. Pet. 19.

By its general terms, and as it was applied to the Activa in particular through the PMA process, 21 C.F.R. § 821.1 required only that Medtronic "adopt a method of tracking" the devices that were implanted in patients. 21 C.F.R. § 821.1(a); see also SA 159. Nothing in the regulation required that Medtronic use the tracking data to issue a voluntary post-sale warning to Activa recipients. Indeed, the regulation itself makes clear that no such requirement existed. As explained in § 821.1(b), the purpose of the tracking

requirement was to ensure "the effectiveness of remedies prescribed by the act," in particular "patient notification" as authorized by 21 U.S.C. § 360h(a) and "device recall" as authorized by 21 U.S.C. § 360h(e). Significantly, the patient notification and the device recall authorized under § 360h both lie within the sole discretion of the Secretary of Health and Human Services; neither provision specifically permits, let alone requires, that a manufacturer act on its own.[14]

Nor is the tracking requirement transformed into a notification requirement by 21 C.F.R. § 814.39, pursuant to which a labeling change that enhances the safety of a device "*may*

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[14] See 21 U.S.C. § 360h(a) ("If *the Secretary* determines that * * * a device * * * presents an unreasonable risk of substantial harm to the public health [and] notification under this subsection is necessary to eliminate * * * such risk, *the Secretary* may issue such order as may be necessary to assure that adequate notification is provided * * * to all health professionals who prescribe or use the device * * * *") (emphasis added); 21 U.S.C. § 360h(e) ("If *the Secretary* finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, *the Secretary* shall issue an order requiring the appropriate person * * * to immediately cease distribution of such device, and * * * to immediately notify health professionals * * * of the order and to instruct such professionals * * * to cease use of such device") (emphasis added). Notably, § 360h(a) expressly contemplates the possibility that a safety notification issued on orders of the Secretary will be withheld from patients themselves, and issued only to their doctors. See 21 U.S.C. § 360h(a) ("An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk *unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification.*") (emphasis added). Thus, contrary to petitioners' suggestion, a requirement that Medtronic, acting on its own, issue a post-sale warning directly to patients cannot be derived from 21 C.F.R. § 821.1.

be placed into effect by the applicant prior to" subsequent FDA approval. 21 C.F.R. § 814.39(d) (emphasis added). The regulation is, by its plain terms, permissive, not prescriptive: it allows, but does not require, a manufacturer to issue post-sale warnings. Indeed, notwithstanding their generalized assertion that Medtronic was required by federal law to issue a post-sale warning to Activa recipients, petitioners acknowledge that § 814.39 "only permits Medtronic to timely warn but doesn't require Medtronic to do so." Pet. 20. See also *id.* at 5 ("Under the FDA regulations at 21 CFR 814.39(d)(1) and (2), Medtronic was *allowed* to immediately send out warnings * * * without prior FDA approval.") (emphasis added); *id.* at 9 ("CFR 814.39(d)(ii) *permitted* Medtronic to issue new warnings to recipients") (emphasis added).

Thus, as the Seventh Circuit properly concluded, neither 21 C.F.R. § 821.1 nor 21 C.F.R. § 814.39, "considered alone or together, imposed upon Medtronic a duty to issue an additional warning between January and March 2001." Pet. App. 12a. Absent a federal requirement affirmatively obligating Medtronic to issue a post-sale warning to Activa recipients, a state-law requirement that Medtronic do the same would be "different from, or in addition to" the applicable federal requirements.[15] Since there was no such federal requirement, petitioners' state-law duty-to-warn claim is, as the Seventh

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[15] Petitioners assert that "[t]he real issue is whether any of the regulations under the Act prevented Medtronic from warning recipients of its deep brain stimulation systems." Pet. 15. That is decidedly *not* the issue. The issue, for preemption purposes, is not whether federal regulations *prevented* Medtronic from issuing a warning, but rather whether any of the requirements imposed through the PMA process *required* Medtronic to issue a warning earlier than it did. If the federal requirements did not require Medtronic to issue a warning, then a state requirement to that effect would necessarily be "different from, or in addition to" the federal requirements.

Circuit correctly held, "preempted pursuant to 21 U.S.C. § 360k(a)." Pet. App. 14a.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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JANUARY 2006

No. 05-682

IN THE
Supreme Court of the United States

JACK McMULLEN and BARBARA McMULLEN,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

REPLY TO BRIEF IN OPPOSITION

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REPLY TO BRIEF IN OPPOSITION

This case presents an important question of federalism. In *Bates v. Dow Argrosciences LLC*, 125 S.Ct. 1788 (2005) this Court stated:

> Even if Dow had offered us a plausible alternative reading of § 136v(b) – indeed. even if its alternative were just as plausible as our reading of that text – we would nevertheless have the duty to accept the reading that disfavors pre-emption. "[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic*, 518 U.S., at 485. In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention "clear and manifest."

While Medtronic, in its index to its Brief in Opposition, notes its references to *Bates* as *Passim* (literally "everywhere" in Latin), an examination of Medtronic's Brief in Opposition reveals that any analysis of the application of the *Bates* decision to the instant action is literally "nowhere" to be found.

In *Bates*, relying upon this Court's seminal decision in *Lohr*, this Court adopted a "parallel requirements" reading of the statute there involved. This Court there stated:

> The "parallel requirements" reading of § 136v(b) that we adopt today finds strong support in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). In addressing a similarly worded pre-emption provision in a statute regulating medical devices, we found that "[n]othing in § 360K denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel

> federal requirements. *Id.*, at 495. As Justice O'Connor explained in her separate opinion, a state cause of action that seeks to enforce a federal requirements "does not impose a requirement that is 'different from, or in addition to,' requirements under federal law. To be sure the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ.

Justice Breyer, who has authored concise and clear (although often misinterpreted) concurring opinions in this area, noted in his concurring opinion in *Bates*:

> In *Medtronic* [citation omitted], I pointed out that an administrative agency, there the Food and Drug Administration, had the legal authority within ordinary administrative constraints to promulgate agency rules and to determine the pre-emptive effect of those rules in light of the agency's special understanding of "whether (or the extent to which) state requirements may **interfere with federal objectives."** *Id.* (emphasis added)
>
> ***
>
> As suggested by *Medtronic*, the federal agency charged with administering the statute is often better able than are courts to determine the extent to which state liability rules mirror or distort federal requirements.

Statutes, as well as cases, are best read from the bottom up. In the instant case, the McMullens' interpretation of the MDA, and the FDA regulations issued thereunder, are wholly consistent with, and in furtherance of, the underlying purpose of the MDA, Medtronic's suggested interpretation is wholly antithetical to it.

The preamble to the MDA sets forth the underlying purpose of the Act: *"to provide for the safety and effectiveness of medical devices intended for human use,"* (emphasis added) 90

Stat. 539. Moreover, the regulations adopted by the FDA were adopted to further that purpose. Under those regulations, manufacturers of Class III medical devices were to:

> Track unexpected adverse events with a device. 21CFR 821.1.
>
> Track devices to patients (including contact information for each recipient) so that they could be quickly notified in the event of unanticipated serious adverse health consequences. 21 CFR 821.1 and section 519(e) of the MDA.
>
> Empower the manufacturer to issue warnings to device recipients (patients) – **without any prior FDA approval**. 21 CFR 814.39

Medtronic's brief is most telling for the points it does not address. It does not, and cannot deny, that it issued a new warning under regulation 814.39 of the Medical Device Act without any prior FDA approval. It does not, and cannot deny, that the sole purpose of that regulation is to enable medical device manufacturers to timely warn of new and serious dangers associated with its products. It does not and cannot deny that it issued the warning in **May** on the basis of the report it knew of in **January**. It also should be noted that Medtronic wholly fails to address the detailed letter of opinion of the FDA's Casper E. Uldricks, Special Assistant to the Director, Office of Compliance, Center for Devices and Radiological Health. (Appendix C to the Petition).

Medtronic's position is that, even though it did issue the warning without FDA approval, even though it issued the warning using regulation 814.39 whose sole purpose is to facilitate timely warning of new dangers, and , even though it waited four months to issue the warning on a danger it knew about in January, it cannot ever be held liable since its actions or inactions are completely shielded from liability under the preemption doctrine.

The purpose and intent of the MDA is to protect the public, including patients like Jack McMullen. It is not to immunize device manufacturers from liability. If the Act were to totally immunize Medtronic and other device manufacturers from civil liability, what incentive would the manufacturer have to follow the scheme set up by the FDA to timely notify patients in danger of serious injury or death? The answer is simple: there would be none.

That answer is clearly demonstrated by the instant case. When Medtronic belatedly — and without any FDA approval — finally issued its warning to medical providers of the dangers of "severe injury or death," on May 16th of 2001, it was not simply issued with regard to its Activa deep brain stimulation implants, but with regard to a whole panoply of its neurological stimulation recipients. (Exhibit F to the McMullens' Response to Medtronic's Motion for Summary Judgment) Moreover, when the warnings to the patients were sent by ordinary mail two days later — again with any prior FDA approval — they were so voluminous that mailings had to be staggered over days. It is clear that there is a vast chasm between how the MDA is intended to function and how Medtronic believes it should function.

As Justice Stevens observed in *Lohr* at 518 US 486-487:

> Medtronic suggests that any common-law cause of action is a "requirement" which alters incentives and imposes duties "different from, or in addition to," the generic federal standards that the FDA has promulgated in response to mandates under the MDA. In essence, the company argues that the plain language of the statute pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices.
>
> Medtronic's argument is not only unpersuasive, it is implausible. Under Medtronic's view of the statute,

> Congress effectively precluded state courts for affording state consumers any protection from injuries resulting from a defective medical device.

Medtronic in this action attempts to dismiss the McMullens by disingenuously asserting contrived admissions that do not survive the light of examination (see Pet. 20), and baldly asserting that the issue advanced is "tired," "stale" and "likely to disappear," all as a substitute for logical argument. In reality not only is there a serious and continuing split among the circuits, but this split is also on an issue that is of increasing importance with an aging population and an increasing use of medical devices. Medtronic has not, and cannot, articulate any valid federal interest under the MDA that is advanced by immunizing device manufacturers from their failure to warn of serious new dangers discovered after the device has reached the patient.

CONCLUSION

For the above reasons, the petitioners respectfully pray that the Supreme Court grant review in this matter.

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